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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,712	WAKAMIYA, NOBUTAKA	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *156-219* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *156-219* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is a reply to the Paper filed 2 May 2005 in response to the Non-Final Office Action mailed 28 October 2004. Claims 156-219 were considered in the 28 October Office Action. No amendments were filed with the 2 May Paper. Claims 156-219 are pending and under consideration.

Response to Arguments

Claim Rejections - 35 USC § 101

Claims 156-219 **stand rejected** under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The rejection was originally set forth in the Office Action 29 April 2003 and is summarized as follows:

On page 47 the specification sets forth the industrial applicability of the claimed invention as, "useful for investigating mechanisms of biological defense systems, and may provide medical, experimental tools in which biological activities of the novel collectin are utilized. For example, vectors that can express the novel collectin, host cells comprising the vector with feasibility of expression, antibodies for the novel collectin, as well as probes for screening the related molecular species of the novel collectin can be provided. In addition, transgenic non-human animals...are provided, which may be utilized as disease model animals for studies on functions, or regulation of expression of the novel collectin". The specification provides no teachings regarding the unique function of the novel collectin (i.e., those functions arising from its novel structure) and only vague statements regarding its role in host defense. As

the specification provides no specific function for the protein and does not identify a single specific condition that could be diagnosed or treated according to the teachings of the specification, it fails to provide a specific utility for the claimed polypeptide, nucleic acid and transgenic animal.

Furthermore, the asserted industrial applicability of the claimed Inventions is mostly directed to identifying the biological activity of the novel collectin and then utilizing the claimed products to diagnose or treat diseases based on that biological activity, whatever it might be. This amounts to an invitation to the skilled artisan to experiment in order to discover the utility of the claimed invention. Therefore the utility provided in the specification is not substantial.

With regard to well-established utility, the specification generally teaches that the novel collectin might be involved in innate immunity based on homology to a family of proteins having Ca^{2+}-dependent carbohydrate recognition regions and collagen-like regions known as collectins. The disclosure teaches only a fragment of the naturally occurring polypeptide, which does not comprise the membrane-spanning domain, and asserts that the disclosed polypeptide is functionally related to a family of soluble proteins. Although it is possible that the extracellular fragment of the naturally occurring novel collectin might have activity similar to a known collectin, the skilled artisan would not be able to identify a well-established utility for the soluble portion of the novel collectin described in the application. Of the known collectins, the sequence set forth as SEQ ID NO:2 is most homologous to SP-D, a collectin found in pulmonary surfactant capable of binding microorganisms and stimulating chemotaxis of phagocytes and production of oxygen radicals (see Hansen *et al.* (1998) *Immunobiol.* 199:165-189, especially the second full paragraph on page 166). However, SEQ ID NO:2 shares only 35% identity with SP-

D over 304 amino acids. The Office Action cites several teachings demonstrating that the art generally acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases such that a specific and substantial utility is readily apparent. The Office Action asserts, given that the structural homology of the instant SEQ ID NO:2 to known collectins is 35%, at best, the function of the extracellular portion of the novel collectin described in the specification would be expected to be related to the function of other collectin family members in broad, general terms which do not suffice to assign a well-established utility to the claimed polypeptide.

In response to the *prima facie* case and arguments set forth in the 28 October Office Action, Applicant first contends that the claimed invention has a well-established utility by virtue of its identification as a collectin. In particular, Applicant points to the teachings at page 1, line 9 to page 2, line 16 of the specification, which, Applicant asserts, describes the known, established properties of collectins. Applicant further cites Figure 5 as showing the alignment of the claimed polypeptide with known collectins.

However, the previous Office Action points out that the claimed material disclosed in the specification is limited sequence homology with a portion of three known collectin molecules; that the alignments provide a comparison of the claimed polypeptide with short fragments of known collectins MBP and SP-A; that the homology with MBP and SP-A proteins is extremely low even over these limited regions; and that the homology with SP-D, the most closely related polypeptide, is only 35% (paragraph bridging pages 7-8). The Office Action refers to the detailed discussion of the relevant art in the 29 April Office Action, which indicates that the degree of homology is too low to establish a specific and substantial utility for the claimed invention.

In response to this, Applicant points out that other recognized members of the collectin family also have low sequence homology and cites examples of SP-D and CL-L1, which have only 29% identity over 264 amino acids, MBP-A and SP-A, which have only 35% identity over 254 amino acids and SP-A and SP-D, which have only 40% identity over 235 amino acids. Based on this, Applicant asserts that the sequence similarity disclosed for the claimed polypeptide supports Applicant's position that the polypeptide is a collectin. Applicant cites the Rule 132 Declaration filed 6 August 2004, which demonstrates that the claimed polypeptide is able to bind galactose in a calcium-dependent manner, as also supporting the assertion that the claimed polypeptide is a collectin and possessing the utilities associated with a collectin. Applicant also cites the teachings of Hoppe and Reid as describing a common structure of collectins and that the Hoppe description is consistent with the claimed polypeptide.

These arguments have been fully considered but are not deemed persuasive. Applicant's arguments appear to be based on an assumption that all collectins have a patentable utility that is readily apparent to one of ordinary skill in the art and merely assigning the polypeptide to the collectin family suffices to meet Applicant's burden under 35 USC §101. Based on the statements in the fourth paragraph on page 2 of the Remarks, it would seem that Applicant views the utility common to all collectins to be therapeutic use as anti-bacterial or anti-viral agents. However, as stated in the previous Office Action, page 8, there is nothing of record that would indicate that any collectin protein has an established therapeutic activity such that one of skill in the art would recognize all members of the collectin family as useful in therapeutic processes. In fact, van de Wetering *et al.*, cited by Applicant as Exhibit A and made of record herein, concludes, after a detailed review of the state of the art approximately five years after the

effective filing date of the instant application, "[a] better understanding of collectin-mediated immunity may in the future allow the identification of disease states in which the therapeutic administration of collectins may be beneficial" (second full paragraph in the right column on page 1241). Furthermore, utilities such as "provid[ing] medical, experimental tools in which biological activities of the novel collectin are utilized", as asserted in the specification, are not specific and substantial utilities unless the biological activities of the novel protein are also disclosed in terms such that the skilled artisan would know specifically the "real world" use to which the medical, experimental tools can be applied (see the paragraph bridging pages 5-6 of the previous Office Action).

Even if therapeutic utility had been established for any one member of the collectin family, there is no evidence that all members of the collectin family would have the same therapeutic activity (*e.g.*, useful in the treatment of the same pathogen). Applicant acknowledges that collectins are a structurally diverse family of polypeptides. Consistent with the art cited in previous Office Actions, which teaches that the functional properties of proteins are related to their structure and proteins having distinct structure also exhibit distinct functional properties, members of the collectin family are known to be functionally diverse. For example, Lu *et al.* (2002) *Biochim. Biophys. Acta* 1572:387-400 teaches that each of the known collectins exhibit a distinct profile of organisms recognized thereby (see especially Table 2). Therefore, even if the collectin SP-D was an established therapeutic for treatment for an organism such as *Mycobacterium tuberculosis*, which it is not, the skilled artisan would not know based on the disclosure that the claimed invention would also be useful in the treatment of *Mycobacterium*

tuberculosis. Therefore, the specific useful properties of the claimed invention are not immediately apparent to the skilled artisan based on what has been disclosed in the application.

Thus, even if one accepts Applicant's assertion that the claimed invention is a member of the collectin family, assignment to this family does not support a well-established utility for what is presently claimed because there is no utility meeting the specific and substantial requirements of 35 U.S.C. §101 common to all members of the collectin family.

Applicant next cites teachings from the post-filing art regarding the scavenger protein CL-P1, which is a membrane-bound collectin involved in the uptake of oxidized LDL particles. Applicant notes that the CL-P1 collectin shares 100% identity to the claimed polypeptide over 547 amino acids; that the polypeptide has been shown to recognize *E. coli* and *S. aureus*; and that the polypeptide preferentially binds galactose over mannose, which was demonstrated to be a property of the claimed polypeptide in the Rule 132 declaration filed 9 August 2004.

These Exhibits and arguments have been fully considered but are not deemed persuasive. It is first noted that art published after the effective filing date of the application is not probative of a well-established utility because the teachings therein were not available to the skilled artisan at the time the application was filed. In particular, at the time of filing, the skilled artisan was unaware of the binding of CL-P1 to LDL particles, *E. coli* and *S. aureus* or the binding of CL-P1 to galactose over mannose and, therefore, would not know that the CL-P1 protein would have any utility related to binding LDL particles, *E. coli*, *S. aureus* or galactose. Furthermore, although the van de Wetering *et al.* reference cited as Exhibit A teaches that CL-P1 binds LDL particles, *E. coli* and *S. aureus*, there is no teaching in van de Wetering *et al.* to suggest that a patentable utility for a soluble fragment of CL-P1, which is what is presently claimed (see

especially the paragraph bridging pages 6-7 of the 29 April 2003 Office Action), would be immediately apparent to one of ordinary skill in the art even in 2004 when van de Wetering *et al.* was published. Thus, the skilled artisan clearly would not have recognized that the fragment of CL-P1 presently claimed would be useful therapeutically as contemplated in the instant application.

Applicant next contends that the fact that a prominent journal accepted and published Applicant's manuscript, which describes CL-P1, is evidence that scientists in the field would regard the molecule as a collectin.

This argument is not persuasive because the requirements for publication in the *Journal of Biological Chemistry* are not the same as the requirements for patentability under 35 USC §101, there is no disclosure of CL-P1 in the instant application (instead the application discloses a soluble fragment thereof; *Id.*), the properties of CL-P1 disclosed in the *Journal of Biological Chemistry* article are not disclosed in the instant application and were not known to the skilled artisan at the time the application was filed, and, as discussed above, there is no patentable utility commonly ascribed to all polypeptides identified as collectins.

In the paragraph bridging pages 4-5 of the remarks, Applicant contends that because the claimed polypeptide binds galactose in a calcium dependent manner, the polypeptide has a specific and substantial utility as a reagent for affinity purifying galactose and galactose-containing complex structures and then releasing the purified structures with changes in calcium.

This argument has been fully considered but is not deemed persuasive. The examiner can find no teaching that the claimed polypeptide can be used as a reagent for affinity purifying galactose and galactose-containing complex structures either in the instant specification or in the

art of record. In fact, it does not appear that the application discloses that the claimed polypeptide binds galactose at all. Therefore, even if one were to assume, *arguendo*, that use as a reagent for affinity purifying galactose and galactose-containing complex structures is a patentable utility, the utility asserted in Applicant's arguments would not have been recognized by the skilled artisan at the time of filing.

Finally, Applicant again cites the teachings at pages 1 and 2 of the specification, which contemplate use of the claimed invention as an anti-viral compound in the inhibition of infection. However, as discussed in previous Office Actions (*e.g.*, page 5 of the 29 April Office Action), this utility is not specific because the Application fails to disclose the unique function of the novel collectin (*i.e.*, those functions arising from its novel structure) and provides only vague statements regarding its role in host defense. As the specification provides no specific function for the protein and does not identify a single specific condition that could be diagnosed or treated according to the teachings of the specification, it fails to provide a specific utility for the claimed polypeptide. Furthermore, as discussed herein above, van de Wetering *et al.* teaches that therapeutic application of collectins remained a subject of investigation and had not been confirmed for any collectin molecule. Thus, therapeutic application of the polypeptide presently claimed would clearly require additional experimentation to reasonably confirm.

In view of these considerations and those set forth in the previous Office Actions, the skilled artisan would not conclude that the utilities asserted in the specification meet the specific and substantial requirements of 35 USC §101, and would not have recognized a specific, substantial and credible utility for the claimed invention which is well known, immediately

apparent, or implied by the specification's disclosure of the properties of a material alone or taken with the knowledge of one skilled in the art at the time the application was filed.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole; therefore, the claims stand rejected under 35 USC §101.

Claim Rejections - 35 USC § 112

Claims 156-219 **stand rejected** under 35 U.S.C. 112, first paragraph, as lacking an enabling disclosure.

As stated in the previous Office Action, since the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if a specific and substantial utility were identified, the skilled artisan would not be able to used the claimed invention as contemplated in the specification without undue experimentation.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

Nature of the invention and Breadth of the claims: The claims are directed to an isolated polypeptide having the amino acid sequence set forth as SEQ ID NO:2 (hereinafter referred to as the novel collectin) and fragments of said polypeptide. Additional claims are directed to polynucleotides encoding the novel collectin and nucleic acids that hybridize with the novel collectin under moderate stringency.

On page 47, the specification sets forth the industrial applicability of the claimed invention as, "useful for investigating mechanisms of biological defense systems, and may provide medical, experimental tools in which biological activities of the novel collectin are utilized. For example, vectors that can express the novel collectin, host cells comprising the vector with feasibility of expression, antibodies for the novel collectin, as well as probes for screening the related molecular species of the novel collectin can be provided. In addition, transgenic non-human animals...are provided, which may be utilized as disease model animals for studies on functions, or regulation of expression of the novel collectin".

Amount of direction provided by the inventor and existence of working examples: The specification discloses the sequence of the polypeptide comprising SEQ ID NO: 2, and the nucleic acid encoding said polypeptide, and generally teaches that the novel collectin might be involved in innate immunity based on homology to a family of proteins having Ca^{2+}-dependent carbohydrate recognition regions and collagen-like regions known as collectins. Figure 5 shows that an alignment of a 210 amino acid fragment of the instant protein with an 85 amino acid fragment of the 248 amino acid MBP, an 87 amino acid fragment of the 248 amino acid SP-A protein and a 207 amino acid fragment of the SP-D protein. The homology to the MBP and SP-A

proteins is extremely low, even over these limited regions, and, as pointed out in previous Office Actions, the homology with SP-D is only 35%.

With regard to using the invention to investigate mechanisms of biological defense systems or to provide medical, experimental tools, the teachings provided are generic in nature and provide no specific teaching as to what properties of biological defense systems can be elucidated, other than the properties of the claimed invention, or how the claimed invention can be used as a tool to solve any specific medical or experimental problem.

State of the prior art and level of predictability in the art: As described in previous Office Actions and herein above, the art available at the time the application was filed did not disclose a polypeptide having the properties of the claimed invention. As described in previous Office Actions, the art generally recognizes that functional properties of a polypeptide cannot be readily predicted based on the properties of polypeptides having similar structure. For example, Skolnick *et al.* (2000) *Trends Biotechnol.* 18:34-39 teach that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating specific details of protein function (see Box 2, page 36). Similarly, Bork (2000) *Genome Res.* 10:398-400 teaches that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially page 399). Smith *et al.* (1997) *Nature Biotechnol.* 15:1222-1223 teaches, "[t]ypical database searching methods are valuable for finding evolutionarily related proteins, but if there are only about 1000 major superfamilies in nature, then most homologs must have different molecular and cellular functions" (second column on page 132). These teaching demonstrate the unpredictability of assigning protein

function based on structure alone; and, given that the structural homology of the instant SEQ ID NO:2 to known collectins is 35%, at best, the function of the extracellular portion of the novel collectin described in the specification would be expected to be related to the function of other collectin family members in broad, general terms.

Furthermore, the art clearly recognizes that therapeutic application of any member of the generic collectin family was highly unpredictable at the time of filing. In particular, van de Wetering *et al.* (*supra*) concludes, after a detailed review of the state of the art approximately five years after the effective filing date of the instant application, "[a] better understanding of collectin-mediated immunity may in the future allow the identification of disease states in which the therapeutic administration of collectins may be beneficial" (second full paragraph in the right column on page 1241).

Relative skill of those in the art and quantity of experimentation needed to make or use the invention: Although the relative level of skill in the art is high, the skilled artisan would not be able to use the claimed invention as asserted in the specification without undue experimentation. Using the claimed invention contemplated in the specification requires that the functional properties of the polypeptide are known in sufficient detail such that the skilled artisan would know how results obtained using the claimed polypeptide or nucleic acid, or reagents developed therewith, elucidate the properties of the innate immune system or would know specifically what conditions could be treated and how those conditions could be treated using the claimed polypeptide or nucleic acid. However, there is no disclosure of the unique properties of the claimed polypeptide or nucleic beyond some limited homology with known members of the collectin family. Given the art recognized unpredictability of establishing protein function based

on similarity to proteins disclosed in databases and the absence of any established use of collectins as therapeutics, the skilled artisan clearly would not be able to use the invention as contemplated without having to engage in undue experimentation to establish the specific useful properties of the claimed polypeptide and nucleic acids.

For these reasons, the disclosure fails to adequately teach the skilled artisan how to use what is claimed. Therefore, the claims stand rejected under 35 USC §112, first paragraph.

Claims 158, 162, 164, 167, 169, 172, 174, 177, 179, 182, 184, 187, 189, 192, 194, 197 and 219 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As stated in the previous Office Action, page 13, the skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acids and polypeptides encompassed by the claims. Therefore, only the nucleic acids and proteins comprising or encoding the polypeptide and nucleic acid sequences explicitly set forth in the disclosure, or the fragments set forth in the claims wherein from 1 to 10 amino acids are deleted substituted or added meet the written description provision of 35 U.S.C. §112, first paragraph.

In response to the *prima facie* case of record, Applicant contends that the claims meet the written description requirement because the specification sets forth the hybridization conditions.

This argument has been fully considered but is not deemed persuasive. The claims were not rejected on the grounds that the application does not disclose the hybridization conditions. As stated in the paragraph bridging pages 12-13, the claimed genera of nucleic acids and polypeptides encompass molecules having shared function and only limited structural similarity. An adequate written description of a molecule requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the molecule itself. Thus, the claims were clearly rejected because the application fails to disclose the claimed nucleic acid, not because the application fails to disclose the hybridization conditions recited in the claims. Therefore, for reasons of record, the claims stand rejected under 35 USC §112 first paragraph as lacking adequate written description.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 203 and 213 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 203 and 213 are directed to a vector and host cell comprising the nucleic acid of claim 177, which was previously rejected under 35 USC §112, first paragraph as lacking written description. As the nucleic acid which defines the invention of claims 203 and 213 is not adequately described in the application, neither is the vector and host cell comprising the nucleic acid. The Guidelines for Written Description state "The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art" (Federal Register, Vol. 66, No. 4, Column 1, page 1105). Therefore, the claims are properly rejected under 35 USC §112, first paragraph, for reasons of record regarding claim 177.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 191, 206 and 216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 191 is directed to an isolated polypeptide according to claim 160 and recites that the polypeptide comprises nucleotides 79-1695 of SEQ ID NO: 1. As claim 160 is directed to a polynucleotide and SEQ ID NO: 1 is a polynucleotide sequence, there is no antecedent basis for a polypeptide comprising nucleotides 79-1695 of SEQ ID NO: 1.

Claims 206 and 216 are indefinite insofar as they depend from claim 191.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M. Sullivan, Ph.D.
Examiner
Art Unit 1636